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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/425,289	10/25/1999	John Luke Toner	REF/TONER/19	9341

7590 08/22/2002

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EXAMINER	
HARTLEY, MICHAEL G	
ART UNIT	**PAPER NUMBER**
1616	20

DATE MAILED: 08/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/425,289	TONER ET AL.	
	Examiner	Art Unit	
	Michael G. Hartley	1616	

-- The MAILING DATE of this communication appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-6 and 8-40* is/are pending in the application.

4a) Of the above claim(s) *8-37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6 and 38-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/27/2002 has been entered.

Response to Amendment

The amendment filed 6/27/2002 has been entered. Claims 4, 6, 38 and 39 have been amended.

Response to Arguments

Any previously set forth rejections that are not reiterated herein have been withdrawn. Applicant's arguments filed 6/27/2002 have been fully considered and are addressed below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-6 and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Sumiaki (JP 63255231), for the reasons set forth in the office action mailed 1/8/2001.

Applicant's arguments filed 6/27/2002 have been fully considered but they are not persuasive.

Applicant asserts that while Sumiaki does disclose the use of imaging to detect the location of the embolus agent, Sumiaki does not disclose that the embolus agent includes a "diagnostically effective compound" in the agent as claimed.

This is not found persuasive because a "diagnostically effective compound" is not limited to a specific type of imaging agent. In fact, applicant defines "diagnostically effective compound" to include any compound which is capable of detection by an imaging modality. The claims only recite that the

diagnostically effective compound is non-radioactive. This is the only limitation thereon. Since the particles themselves act as a diagnostically effective imaging agent, the particles disclosed by Sumiaki contain such a compound. Particles themselves are often used as imaging agents or diagnostically effective compounds in the art of imaging (e.g., non-radioactive imaging), as are gases or voids which are entrapped in particles, such as porous particles, therefore particles (e.g., including the compounds in which they are made of and including air in voids contained therein) are within the scope of diagnostically effective compounds, given the broadest reasonable interpretation thereof. Thus, the particles disclosed by Sumiaki comprise all of the components as claimed, a diagnostically effective compound (the hydroxy calcium apatite particles, e.g., which are a known diagnostic agent and are detected in the invention of Sumiaki) and a non-polymeric matrix encapsulate (e.g., the carcinostatic agent).

Applicant further asserts that there is no disclosure or suggestion of any diagnostic utility for the Sumiaki particles.

This is not found persuasive because the instant claims are not drawn to a method of imaging, but rather to a "method of embolus therapy" which is disclosed by Sumiaki. The examiner's position rests on the interpretation of "non-radioactive diagnostically effective compound" which is being interpreted by the examiner as any compound which is capable of being detected diagnostically and is not limited to any specific diagnostic compound, (or to require any method steps that a specific type of imaging is performed, as the claims do not include an imaging step). The diagnostically effective compound in the claim is defined by function only (e.g., it is diagnostically effective), thus any compound that can be detected diagnostically is encompassed thereby. This recitation does not even require a specific means of how such diagnosis is effected. The particles disclosed by Sumiaki are detected diagnostically *in vivo*, therefore, they must include a compound which performs this function (e.g., the apatite which is part of the particle). Since the particles disclosed by Sumiaki are diagnostically detectable by non-radioactive means, they inherently contain a (non-radioactive) diagnostically effective compound. For example, since the particles themselves are diagnostically detected, the particles must contain a compound which is diagnostically effective.

Claims 2-6 and 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsuru (US Pat. 5,055,307), for the reasons set forth in the office action mailed 1/8/2001.

Applicant's arguments filed 6/27/2002 have been fully considered but they are not persuasive.

Applicant asserts that while Tsuru suggests that the particles may be used for imaging purposes, the reference provides no suggestion that the particles could be used for diagnostic imaging or contain a diagnostic imaging agent as claimed.

There is no distinction made between an "imaging agent" and a "diagnostic imaging agent" given the broadest reasonable interpretation thereof. All imaging agents are considered to be a diagnostic tool, even if the diagnosis is to identify the administration of the embolic agent. The term "diagnostically effective" does not limit the compound to having a certain type of diagnostic function other than imaging nor does it limit the compound to specific compounds which exclude the compounds disclosed by Tsuru which are capable of being imaged (a diagnostic method) *in vivo*. The specification defines "diagnostically effective compounds" as any compound which is detectable by imaging, e.g., page 5, last paragraph. Clearly, the particles disclosed by Tsuru are detectable by imaging.

Applicant further asserts that the particles themselves are diagnostically effective, and do not contain an imaging agent (diagnostically effective agent).

This is not found persuasive because particles are often a diagnostically effective agent themselves, therefore contain a diagnostically effective compound. Thus, they must contain a diagnostically effective compound which makes up the particle. The term "diagnostically effective compound" does not exclude particles themselves, since particles are often used in the art as diagnostically effective compounds (e.g., ultrasound imaging agents, etc.). However, Tsuru also discloses the use of an iodinated contrast agent in example 1, which is clearly within the scope of a diagnostically effective compound, as claimed.

Applicant further asserts that there is no disclosure about the nature of the pores and/or whether or not the contrast agent might or might not be admitted into the particle matrix.

This is not found persuasive because the main reason for the pores in the particles is to impregnate various active agents, which would include the imaging agent, e.g., column 5, lines 15+.

However, since the porous particles themselves are diagnostically effective, they must contain a diagnostically effective compounds, such as, the pores, which provide for diagnostic effectiveness using ultrasound imaging, see abstract and columns 1-2.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 2-6 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over either one of Sumiaki (JP 63255231) or Tsuru (US Pat. 5,055,307) in view of Meeh (WO 95.27437), for the reasons set forth in the office action mailed 1/8/2001.

Applicant's arguments filed 6/27/2002 have been fully considered but they are not persuasive.

Applicant asserts that this rejection falls since the primary references do not disclose the claimed method, as argued.

This is not found persuasive because the primary references do disclose a method that is encompassed by the claims for the reasons, as addressed above.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons set forth in the office action mailed 7/25/2001.

Applicant argues that this claim is clear because the claim refers back to claim 38 which recites water insoluble particles and therefore the water insoluble particles would include the phosphate salt having the recited formula.

This is not found persuasive due to the use of the "consisting essentially of" terminology in base claim 38. Base claim 38 states that the water insoluble particles "consist essentially of" two component, a "non-radioactive diagnostically effective compound" and a "non polymeric particulate matrix" and it is unclear how the particles can also comprise a phosphate salt having the formula claimed, given that "consisting essentially of" is somewhat closed claim language. It appears that the phosphate salt (is further defining "the non-polymeric particulate matrix" as set forth in the base claim (claim 38). This rejection may be overcome by amending claim 5 to state wherein said "A method of claim 38, wherein said non-polymeric particulate matrix is an insoluble phosphate salt of the formula..." to clarify.

Conclusion

No claims are allowed at this time.

This is a RCE of applicant's earlier Application No. 09/425,289. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Michael G. Hartley
Primary Examiner
Art Unit 1616

MH
August 20, 2002